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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,372	12/21/2001	Roger A. Sabbadini	078853-0302	3592

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EXAMINER

LEARY, LOUISE N

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 02/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,372

Applicant(s)

SABBADINI, ROGER A.

Examiner

Louise N. Leary

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 May 2002 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2. 6) ☐ Other: .

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1. Claims 1-20 are pending in this application.
2. Claims 1 and 5-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 5-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: descriptions of a host or sample.

Correction is required to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marangos (US 5,677,288) in view of Webster' Dictionary (1990).

Marangos discloses a method relating "...to pharmacology and neurology, and involves drugs that can prevent or reduce nerve cell death or damage due to conditions such as stroke, drowning, cardiac arrest, or various injuries or diseases." See column 1, lines 12-17. Marangos discloses that the method involves administering an aminoglycoside. Also, Marangos specifically discloses administering gentamicin. Regarding the kind of cardiovascular and/or

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cerebrovascular disorders claimed in the instant invention, Marangos discloses administering aminoglycosides during in vitro and in vivo testing of mammalian neuronal tissue from mammals having a variety of neuronal conditions. Ischemia was a condition treated with the aminoglycoside and described in the Marangos disclosure. Note the abstract; column 27, lines 31-65 and column 28, lines 1-63. Thus, Marangos discloses the invention claimed except for stating the aminoglycoside agent alters the activity or concentration of enzyme that produces or degrades a sphingolipid or a sphingolipid metabolite.

However, regarding sphingolipid claim limitations in the present invention, Webster defines "sphingosine" as a long-chain unsaturated amino alcohol $C_{18}H_{37}O_2N$ found esp. in nervous tissue and cell membranes". Note page 1135. It is noted that Webster's dictionary sufficiently described the presence of sphingosine in nervous tissue and cell membranes before this invention was made.

Hence, Marangos discloses the invention claimed except for addressing the enzymatic activity of aminoglycoside on sphingolipid or sphingolipid metabolite which was provided Webster's dictionary definition of "sphingosine" that sufficiently described the presence of sphingosine in nervous tissue and cell membranes prior to the time this invention was made.

It would have been obvious to one having ordinary skill in this art at the time this invention was made to provide the method, pharmaceutical composition and formulation invention claimed because Marangos discloses the method steps for administering aminoglycosides, aminoglycoside pharmaceutical compositions and formulations claimed in the instant invention claimed except for stating the aminoglycoside agent alters the activity or concentration of enzyme that produces or degrades a sphingolipid or a sphingolipid metabolite

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which was addressed by Webster's Dictionary definition of "sphingosine as a long-chain unsaturated amino alcohol $C_{18}H_{37}O_2N$ found esp. in nervous tissue and cell membranes" that is herein deemed to render this invention obvious due to a showing of sufficient evidence relating the presence of sphingosine in nervous tissue and cell membranes before this invention was made.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (703) 308-3533. The examiner can normally be reached on Monday to Friday from 9:30 to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703)308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-1235.

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LOUISE N. LEARY
PRIMARY EXAMINER

February 22, 2003